FEB 6 2006

510(k) Summary
Emit® 2000 Cyclosporine Specific Assay

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K053061

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Dade Behring Inc. 20400 Mariani Ave. Cupertino, CA 95014
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714 Attn: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	Oct. 14, 2005

2. Device Name / Classification

Emit® 2000 Cyclosporine Specific Assay / Class II

3. Identification of the Predicate Device

Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood Assay, P890025

4. Device Description

The Emit® 2000 Cyclosporine Specific Assay employs a homogeneous enzyme immunoassay technique used for the analysis of cyclosporine in whole blood. The assay contains mouse monoclonal antibodies with a high specificity for cyclosporine.

The Emit® 2000 Cyclosporine Specific Assay is based on competition for cyclosporine antibody binding sites. Cyclosporine in the sample competes with cyclosporine in Enzyme Reagent B that is labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH). Active (unbound) enzyme converts the oxidized nicotinamide adenine dinucleotide (NAD) in Antibody Reagent A to NADH, resulting in a kinetic absorbance

change that can be measured spectrophotometrically. Enzyme activity decreases upon binding to the antibody, allowing the cyclosporine concentration in the sample to be measured in terms of enzyme activity. Endogenous serum G6PDH does not interfere because the coenzyme NAD functions only with the bacterial (Leuconostoc mesenteroides) enzyme employed in the assay.

5. Device Intended Use

The Emit® 2000 Cyclosporine Specific Assay is for in vitro quantitative analysis of cyclosporine (CsA) in human whole blood as an aid in the management of cyclosporine therapy in kidney, heart and liver transplant patients.

6. Medical device to which equivalence is claimed and comparison information

The Emit® 2000 Cyclosporine Specific Assay is substantially equivalent in intended use and technological characteristics to the Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood Assay. Both devices are immunoassays intended for use in the quantitative measurement of cyclosporine in human whole blood. The Emit® 2000 Cyclosporine Specific Assay has an assay range of 40-500 ng/mL or 350-2000 ng/mL. The Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood Assay has an assay range of 25-1500 ng/mL

Comparison Information

Method comparison studies were conducted at two external sites comparing the extended range Emit® 2000 Cyclosporine Specific Assay against two predicates:

- the Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood Assay, and
- liquid chromatography / mass spectrometry (LC/MS)

Banked retrospective samples from 3 transplant patient groups (heart, liver and kidney) were used in the studies. The data from both sites were pooled and analyzed by linear regression.

Comparative Method LC/MS	Slope	Intercept	r	n
All samples	1.01	36.07	0.971	138
Heart	1.04	19.00	0.989	33
Liver	1.00	42.11	0.971	40
Kidney	1.14	-49.0	0.951	59
Abbott TDx®/TDx/FLx® CSA Monoclonal Whole Blood Assay				
All samples	1.13	-92.4	0.969	134
Heart	1.12	-86.6	0.976	33
Liver	1.14	-102	0.982	40
Kidney	1.15	-114	0.950	59

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 6 2006

Yuk-Ting Lewis
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
M/S 514
Newark, DE 19714

Re: k053061
Trade/Device Name: Emit®2000 Cyclosporine Specific Assay
Regulation Number: 21 CFR§ 862.1235
Regulation Name: Cyclosporine test system
Regulatory Class: Class II
Product Code: MKW
Dated: January 6, 2006
Received: January 13, 2006

Dear Yuk-Ting:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Emit® 2000 Cyclosporine Specific Assay**

Indications For Use:

The Emit® 2000 Cyclosporine Specific Assay is for in vitro quantitative analysis of cyclosporine (CsA) in human whole blood as an aid in the management of cyclosporine therapy in kidney, heart and liver transplant patients.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ann Chappie

Office of In Vitro Diagnostic Device
Evaluation and Safety

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